REMARKS

Applicant respectfully requests reconsideration.

Claims 1-13, 15-17, 22-33, 35-38, 40-51, 53-62 and 67-74 were previously pending in this application. By this amendment, Applicant has amended claim 1 and has canceled claim 2 without prejudice or disclaimer. Support for the claim amendments can be found in the claims as originally filed. As a result, claims 1, 3-13, 15-17, 22-33, 35-38, 40-51, 53-62 and 67-74 are pending for examination with claims 1 and 40 being independent claims.

No new matter has been added.

Full Faith and Credit

The instant application was filed almost seven years ago, and up until the pending office action, Applicant's assignee's representative had been prosecuting the instant application with the same Examiner. Additionally, it had been believed that allowance was about to be achieved with the previous Examiner. Instead, however, the instant application has been reassigned to a new Examiner who has taken an entirely new approach and appears to have made a new search.

Applicant wishes to note for the record that full faith and credit should be given to the search and action of the previous examiner. MPEP 706.04. In general, an examiner should not take an entirely new approach or attempt to reorient the point of view of a previous examiner, or make a new search in the mere hope of finding something. Amgen, Inc. v. Hoechst Marion Roussel, Inc., 126 F. Supp. 2d 69, 139, 57 USPQ2d 1449, 1499-50 (D. Mass. 2001).

Accordingly, Applicant respectfully requests that the new Examiner keep this in mind when considering the instant application.

Objection to the Specification

The Examiner requested that the specification be amended to include the issued patent number of the parent application.

Applicant has amended the specification based on the Examiner's suggestion. Accordingly, it is believed that this objection is now moot.

IDS

Applicant thanks the Examiner for his acknowledgement of the previously filed Information Disclosure Statement (IDS). As the Examiner has crossed out a few of the references, Applicant is submitting herewith another IDS citing the crossed out references with their dates of publication.

Rejections under 35 U.S.C. §112

Claim 12 is rejected under 35 U.S.C. §112, second paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner has indicated that claim 12 has no antecedent basis in claim 1.

Applicant respectfully traverses. Claim 1 recites an administering step, and claim 12 indicates that a mammalian cell with a surface exposed MBL ligand is contacted with the MBL inhibitor. It would be clear to one of ordinary skill in the art based on the plain language of the claims and the teachings provided in the specification that the antecedent basis for claim 12 is derived from the administering step of claim 1. Accordingly, the written description is satisfied.

Reconsideration and withdrawal of this rejection is respectfully requested.

Claims 1-13, 15-17, 22-33, 35-38, 40-51, 53-62 and 67-74 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner has indicated that the specification fails to describe the claimed invention in a way that would convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, has possession of the claimed invention.

Applicant respectfully traverses. In order to maintain this rejection, the Examiner must demonstrate that one of ordinary skill in the art would be unable to recognize that which is being claimed. Applicant maintains that the Examiner has failed to make such a demonstration. For this reason alone, the rejection should not be maintained.

In addition, the specification provides a sufficient description of the MBL inhibitors of the claims. For example, the specification describes, on page 3, lines 23-27, MBL-binding peptides that have a MBL-binding CDR3 region and provides that MBL-binding peptides can be

antibodies or antibody fragments. On page 4, line 24 through page 5, line 24, the specification again teaches that MBL-binding peptides can have a CDR3 from the three deposited antibodies, and that the MBL-binding peptides can be intact soluble monoclonal antibodies, humanized antibodies or antibody fragments. On page 18, lines 28-31, the instant specification teaches that the CDR regions, and in particular the CDR3 region, can be incorporated into other antibodies. Further, humanized monoclonal antibodies that contain a CDR3 region from the deposited antibodies are provided on page 21, line 4 through page 23, line 2. Antibody fragments, including humanized monoclonal antibody fragments are described on page 25, line 3 through page 26, line 29.

The instant specification also teaches that several peptides which bind to MBL or MASP have been described in the art, including Lanzrein, A.S. et al., "Mannan-binding lectin in human serum, cerebrospinal fluid and brain tissue and its role in Alzheimer's disease", Department of Pharmacology, University of Oxford, UK, May 11, 1998, Neuroreport, 9(7):1491-5; Jack, D.L. et al., "Activation of complement by mannose-binding lectin on isogenic mutants of Neisseria meningitidis serogroup B", Immunobiology Unit, Institute of Child Health, London, UK, *J Immunol*, February 1, 1998,160(3):1346-53, Terai, I. et al., "Human serum mannose-binding lectin (MBL)-associated serine protease-1 (MASP-1): determination of levels in body fluids and identification of two forms in serum", Division of Clinical Pathology, Hokkaido Institute of Public Health, Sapporo, Japan, Clin. Exp. Immunol., Nov., 1997, 110(2):317-23; Endo, M. et al., "Glomerular deposition of mannose-binding lectin (MBL) indicates a novel mechanism of complement activation in IgA nephropathy [In Process Citation]", Second Department of Internal Medicine, Nihon University School of Medicine, Tokyo, Japan, Nephrol Dial Transplant, August 13, 1998, (8):1984-90; Valdimarsson, H. et al., "Reconstitution of opsonizing activity by infusion of mannan-binding lectin (MBL) to MBL-deficient humans", Department of Immunology, University of Reykjavik, Iceland, Scand. *J. Immunol.*, August 1998, 48(2):116-23; and Thiel, S. et al., "The concentration of the C-type lectin, mannan-binding protein, in human plasma increases during an acute phase response", *Clin Exp. Immunol.*, Oct. 1992, 90(1):31-5.

With at least the above-described support found in the instant specification, one of ordinary skill in the art would clearly recognize a description of the claimed subject matter, and, therefore, the instant disclosure adequately describes the claimed invention such that one of

ordinary skill in the art would recognize that Applicant, at that time the instant application was filed, had possession of the claimed invention.

Reconsideration and withdrawal of this rejection is respectfully requested.

Claims 1-13, 15-17, 22-33, 35-38, 40-51, 53-62 and 67-74 are rejected under 35 U.S.C. §112, first paragraph, for allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed invention.

Applicant respectfully traverses. In order to maintain this rejection, the Examiner must demonstrate that one of ordinary skill in the art would be required to perform undue experimentation to practice the claimed invention. The Examiner's rejection fails, as a sufficient basis to challenge Applicant's teachings has not been provided.

First, all but the cited Collard et al. reference are not relevant to the claimed methods for inhibiting LCP complement activation. From these references, therefore, it is not reasonable to doubt Applicant's teachings and to draw a negative conclusion in regard to the enablement of the specifically claimed methods. Second, Applicant respectfully wishes to bring to the Examiner's attention that the cited Collard et al. reference describes the inventors' own work and demonstrates that the inventors generated three monoclonal antibodies that "were very potent inhibitors of MBL deposition after endothelial oxidative stress" (as stated in the second to last paragraph of the article.) Finally, even if the claims encompass yet to be identified inhibitors, such is not the standard by which to challenge enablement.

Accordingly, based on the teachings provided in the instant specification and the level of skill of those of ordinary skill in the art, one of ordinary skill would need use only routine experimentation to practice the claimed methods, and the Examiner has not established otherwise.

Reconsideration and withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. §102

Claims 1-2, 12, 30-33, 38, 40, 50, 51, 56 and 60-62 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 5,270,199.

Applicant respectfully traverses. In order to be inherently anticipated the recited prior art must necessarily achieve the claimed invention each and every time the recited prior art is practiced. The Examiner has failed to establish that this is the case. The Examiner merely states that the MBP protein would bind to MASP in the absence of evidence to the contrary. However, the Examiner is respectfully reminded that the claims are directed to a method for inhibiting lectin complement pathway (LCP) associated complement activation mediated cellular injury. Therefore, it must be established that the practice of the prior art would necessarily achieve such inhibition each and every time the prior art is practiced.

Reconsideration and withdrawal of this rejection is respectfully requested.

Claims 1-2, 12, 30-33, 38, 40, 50, 51, 56 and 60-62 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Fischer et al. (Scand. J. Immunol. 39:439-45, 1994).

Applicant respectfully traverses. Again, in order to establish inherent anticipation the recited prior art must necessarily achieve the claimed invention each and every time the recited prior art is practiced. The Examiner has not demonstrated that this is the case. The Examiner has tried to argue that Fischer et al. teach the administration to the same subjects of the claims, but has not offered any evidence outside of his opinion as to why this is the case.

Reconsideration and withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. §103

Claims 1-2, 6, 12, 13, 15, 25, 26, 30-33, 35, 38, 40, 44, 50, 51, 53, 56, 57, 60-63 and 70-71 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Endo et al. (Nephrol Dial Transplant. 1998 Aug; 13(8):1984-90).

Applicant respectfully traverses. The Examiner has not demonstrated that the teachings of Endo et al. teach or suggest the administration of an MBL inhibitor to a subject with a cellular injury to inhibit LCP complement activation mediated cellular injury. Without such a demonstration this rejection cannot be maintained.

Reconsideration and withdrawal of this rejection is respectfully requested.

Claims 1-2, 6, 12, 13, 15, 25, 26, 30-33, 35, 38, 40, 44, 50, 51, 53, 56, 57, 60-63 and 70-71 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Malhotra et al. (Nat Med. 1995(3):237-43) in view of Endo et al. (Nephrol Dial Transplant. 1998 Aug; 13(8):1984-90).

Applicant respectfully traverses. As argued above, the Examiner has not demonstrated that Endo et al. teach or suggest the administration of an MBL inhibitor to a subject with a cellular injury to inhibit LCP complement activation mediated cellular injury. As this rejection relies on Endo et al., this rejection cannot be maintained.

Reconsideration and withdrawal of this rejection is respectfully requested.

Claims 1-2, 6, 12, 13, 15, 25, 26, 30-33, 35, 38, 40, 44, 50, 51, 53, 56, 57, 60-63 and 70-71 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Matsuda et al. (Journal of Nephrology Association of Japan 39(3):235 (1997)) optionally in view of Endo et al. (Nephrol Dial Transplant. 1998 Aug; 13(8):1984-90).

Applicant respectfully traverses. The Examiner has not demonstrated that either Matsuda et al. or Endo et al. teach or suggest the administration of an MBL inhibitor to a subject with a cellular injury to inhibit LCP complement activation mediated cellular injury. Accordingly, this rejection cannot be maintained.

Reconsideration and withdrawal of this rejection is respectfully requested.

Claims 22-23, 25-26, 28-29, 36-37, 54-55, 67-68 and 73-74 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Endo et al. (Nephrol Dial Transplant. 1998 Aug; 13(8):1984-90) as applied to claims 1, 13, 33, 40, 51 and 70 and further in view of Owens et al.

Applicant respectfully traverses. As argued above, the Examiner has not demonstrated that Endo et al. teach or suggest the administration of an MBL inhibitor to a subject with a cellular injury to inhibit LCP complement activation mediated cellular injury. As this rejection relies on Endo et al., this rejection cannot be maintained.

Reconsideration and withdrawal of this rejection is respectfully requested.

Claims 22-23, 25-26, 28-29, 36-37, 54-55, 67-68 and 73-74 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Malhotra et al. (Nat Med. 1995(3):237-43) in view of Endo et al. (Nephrol Dial Transplant. 1998 Aug; 13(8):1984-90) as applied to claims 1, 13, 33, 40, 51 and 70 and further in view of Owens et al.

Applicant respectfully traverses. As argued above, the Examiner has not demonstrated that Endo et al. teach or suggest the administration of an MBL inhibitor to a subject with a cellular injury to inhibit LCP complement activation mediated cellular injury. As this rejection relies on Endo et al., this rejection cannot be maintained.

Reconsideration and withdrawal of this rejection is respectfully requested.

Claims 22-23, 25-26, 28-29, 36-37, 54-55, 67-68 and 73-74 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Matsuda et al. (Journal of Nephrology Association of Japan 39(3):235 (1997)) optionally in view of Endo et al. (Nephrol Dial Transplant. 1998 Aug; 13(8):1984-90) as applied to claims 1, 13, 33, 40, 51 and 70 and further in view of Owens et al.

Applicant respectfully traverses. As argued above, the Examiner has not demonstrated that either Matsuda et al. or Endo et al. teach or suggest the administration of an MBL inhibitor to a subject with a cellular injury to inhibit LCP complement activation mediated cellular injury. As this rejection relies on Matsuda et al. or Endo et al., this rejection cannot be maintained.

Reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. A0752.70001US01.

Respectfully submitted,

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